RENOVIS

Abbreviated 510(k) Summary
as required by 21 CFR 807.92(a)
K131122

A) Submitted by: Renovis Surgical Technologies
1901 W. Lugonia Ave, Ste 340
Redlands, CA 92374
Phone: 909-557-2360
Fax: 909-307-8571

Official Contact: Anthony DeBenedictis
Vice President of Quality Assurance

Consultant: Sharyn Orton, Ph.D.
MEDIcept, Inc. 200
200 Homer Ave
Ashland, MA 01721

SEP 18 2013

Date Prepared: September 16, 2013

B) Device Name: Intervertebral Fusion Device With Bone Graft, Lumbar

Common Name: Intervertebral body fusion device

Proprietary Name: S128 Anterior Lumbar Interbody Fusion (ALIF) System

Device Class: Class II – 888.3080

Regulation and Product code: 888.3080, OVD - Intervertebral body fusion device

Classification panel: Orthopedic

C) Predicates:

- K081177 Blackstone Orthofix Pillar
- K092211 K2M Chesapeake
- K123767 Lanx Lateral –SA System
- K102738 Lanx Fusion System
- K083815 Lanx Fusion System
- K073144 Lanx Intervertebral Body Fusion Device
- K082260 Calvary Spine Petra PLIF Cage System

RENOVIS

D) Device Description:

The Renovis S128 Anterior Lumbar Interbody Fusion (ALIF) System is to be used with the bone screws and anterior cover plate assembly and requires no additional supplementary fixation systems. The screws protrude through the interbody portion of the device and stabilize the vertebral body while preventing expulsion of the implant. The Renovis S128 ALIF System contains both fixed and variable angle screw options. The fixed angle screw option provides a tight fit with the cage. The variable angle screw option provides a slight clearance between the cage and the screw which allows for a small amount of variable screw angulations.

The Renovis S128 ALIF System cages are intended to be used with autogenous bone graft. The accompanying cover plate is designed to prevent screw back-out and must be used when the screws are implanted. NOTE: The cover plate assembly and screw are part of the implant construct.

The Renovis S128 ALIF System implants are available in a variety of sizes (widths, height, depths, and bone screw sizes) to suit the individual pathology and anatomical conditions of the patient. The implants are manufactured from PEEK or additively manufactured and machined Titanium. The bone screws and coverplate assembly are both manufactured from Titanium alloy. The PEEK markers are manufactured from Tantalum. The Renovis S128 ALIF System is used with trials and implant specific manual instruments, and includes other class I manual orthopedic instruments.

E) Indications For Use:

The Renovis S128 Anterior Lumbar Interbody Fusion (ALIF) System is indicated for intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) of the lumbar spine at one or two contiguous levels from L2-S1. Degenerative disc disease is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These DDD patients may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). Renovis S128 ALIF System implants are to be used with autogenous bone graft.

Patients should be skeletally mature and have at least six months of non-operative treatment.

The Renovis S128 ALIF System is a stand-alone device and is intended to be used with the cover plate and screws provided and requires no additional supplementary fixation. The anterior cover plate must be utilized whenever the device is implanted using the bone screws provided. Should the physician choose to use fewer than the four screws provided, additional supplemental fixation cleared by the FDA for use in the lumbar spine must be used.

F) Substantial Equivalence Comparison and Discussion

	Renovis S128 ALIF System	Blackstone (Orthofix) Pillar K081177	K2M Chesapeake K092211	Lanx Lateral SA System K123767 Fusions System K102738 Fusion System K083815 Intervertebral body Fusion Device K073144	Calvary Spine Petra PLIF Cage System K082260
Implant Material	PEEK Titanium	PEEK	PEEK	PEEK Titanium alloy	PEEK
Dimensions in mm A/P M/L H	 26, 28, 30 30, 34, 38 11 - 21	 28, 32 37, 40, 43 12.5 - 20	 24, 28, 30 30, 36, 40 11-19	 16, 18, 22, 26 25 to 60 6-16	 Crescent 13x 27 Straight 11 x 30 7-15
Lordosis	7°, 12°	7°, 12°	$10^0, 15^0$	$0^0, 8^0$	8^0
Screw material	Titanium	Titanium	Titanium	Titanium when applicable	Requires supplemental fixation
Number of screws	4	4	3	Unk	
Screw Diameter (mm)	4.5, 5.0	5.0, 5.5	5.5	Unk	
Screw Length (mm)	20, 25, 30, 35	20, 25, 30, 35	20, 25, 30	Unk	
Cover plate	Titanium	Titanium	Titanium	Unk	
Marker material	Tantalum	Tantalum	Tantalum	Tantalum	Tantalum

Conclusion

Based upon the same or similar intended use, design, function, technology, and materials, the Renovis S128 ALIF System is substantially equivalent to the predicate devices and does not raise new issues of safety or effectiveness.

G) Performance Testing

The Renovis S128 ALIF System implants (worse case constructs) have successfully undergone the following testing:

1. Static Compression per ASTM F2077
2. Dynamic Compression per ASTM F2077
3. Static Shear-Compression per ASTM F2077
4. Dynamic Shear-Compression per ASTM F2077
5. Expulsion Testing w/screws per ASTM Draft Standard F04.25.02.02
6. Expulsion Testing w/o screws per ASTM Draft Standard F04.25.02.02
7. Subsidence testing per ASTM F2267

Sample coupons of the Titanium porous structure have successfully undergone the following testing:

1. Shear testing of metallic coatings per ASTM F1044
2. Tensile testing of metallic coatings per ASTM F1147
3. Abrasion per ASTM F1978
4. Porosity and microstructure per ASTM F1854

Conclusion

Performance data results support that the Renovis S128 ALIF System is substantially equivalent to the predicate devices and that there are no new issues of safety or effectiveness.

H) Compliance with FDA Guidance and Consensus Standards

The Renovis S128 ALIF System complies with the following:

FDA Guidance:

- Guidance Document Guidance for Industry and FDA Staff - Class II Special Controls Guidance Document: Intervertebral Body Fusion Device", June 12, 2007.
- Guidance for Industry and FDA Staff: Spinal System 510(k)s", May 2004 for labeling including labels, Instructions for Use and Surgical Manual

21 CFR 888.3080 Intervertebral body fusion device:

- ASTM F 983-86 (Reapproved 2009) Standard Practice for Permanent Marking of Orthopaedic Implant Components

- ASTM F 565-04 (Reapproved 2009)e1 Standard Practice for Care and Handling of Orthopedic Implants and Instruments
- ASTM F2267-04 Standard Test Method for Measuring Load Induced Subsidence of an Intervertebral Body Fusion Device Under Static Axial Compression
- ASTM F2077-3 Test Methods for Intervertebral Body Fusion Devices

Other

- ASTM F2026 Standard Specification for PEEK Polymers for Surgical Implant Applications
- ASTM F-136 Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications, and
- ASTM F 560-08, Standard Specification for Unalloyed Tantalum for Surgical Implant Applications
- ASTM draft standard F.04.25.02.02 Static Expulsion
- ASTM F1044-05(2011)e1 Standard Test Method for Shear Testing of Calcium Phosphate Coatings and Metallic Coatings
- ASTM F1147- 05(2011) Standard Test Method for Tension Testing of Calcium Phosphate and Metallic Coatings
- ASTM F1978 – 12 Standard Test Method for Measuring Abrasion Resistance of Metallic Thermal Spray Coatings by Using the Taber Abraser
- ASTM F1854 - Standard Test Method for Stereological Evaluation of Porous Coatings on Medical Implants
- ASTM A564 - Standard Specification for Hot-Rolled and Cold-Finished Age-Hardening Stainless Steel Bars and Shapes
- ASTM F138 - Standard Specification for Wrought 18Chromium-14Nickel-2.5Molybdenum Stainless Steel Bar and Wire for Surgical Implants

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

September 18, 2013

Renovis Surgical Technologies, LLC
% Sharyn Orton, Ph.D.
MEDIcept, Incoporated
200 Homer Avenue
Ashland, Massachusetts 01721

Re: K131122
Trade/Device Name: Renovis S128 Anterior Lumbar Interbody Fusion (ALIF) System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: OVD
Dated: August 16, 2013
Received: August 19, 2013

Dear Dr. Orton.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Ronald P. Jean -S for

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): K131122

Device Name: Renovis S128 Anterior Lumbar Interbody Fusion (ALIF) System

Indications for Use:

The Renovis S128 Anterior Lumbar Interbody Fusion (ALIF) System is indicated for intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) of the lumbar spine at one or two contiguous levels from L2-S1. Degenerative disc disease is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These DDD patients may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). Renovis S128 ALIF System implants are to be used with autogenous bone graft.

Patients should be skeletally mature and have at least six months of non-operative treatment.

The Renovis S128 ALIF System is a stand-alone device and is intended to be used with the cover plate and screws provided and requires no additional supplementary fixation. The anterior cover plate must be utilized whenever the device is implanted using the bone screws provided. Should the physician choose to use fewer than the four screws provided, additional supplemental fixation cleared by the FDA for use in the lumbar spine must be used.

Prescription Use___X_____ AND/OR Over-the-Counter Use _____
(21 CFR 801, Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of *CDRH, Office of Device Evaluation (ODE)*

Anton E. Dmitriev, PhD
Division of Orthopedic Devices